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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,325	12/12/2000	Steven S. Hackett	S63.2-9222	4944

490 7590 05/20/2003

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER
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PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/20/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

N.R.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/735,325	HACKETT ET AL.
	Examiner	Art Unit
	Brian E Pellegrino	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 10 March 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) 3-7 and 9 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,2,8 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 12 December 2000 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on 0 is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) Other:

## DETAILED ACTION

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "lubricious substance" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is an inconsistency between the language of the preamble that recites "an elastomeric sleeve" and certain portions in the body of the claim that recites, "a lubricious substance". Therefore, the scope of the claim is unclear as to what is intended to be claimed, the subcombination (sleeve) or the combination of the sleeve and the lubricious substance. The language of the claim must be consistent with the intent.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Konya et al. (6123723). Konya et al. disclose elastomeric material for a sleeve for retaining a stent, col. 17, lines 22-26. Konya also discloses fluid openings or “ports” are in the sleeve to deliver a fluid material to aid in positioning the stent, col. 22 lines 57-61. The openings are fully capable of allowing a lubricious substance to pass through them. Claims in a pending application should be given their broadest reasonable interpretation. *In re Hyatt*, 211 F.3d 1367, 54 USPQ2d 1664 (Fed. Cir. 2000). Therefore, a “lubricious” substance can be saline or contrast medium since they reduce friction between the balloon and sleeve.

Claims 1,2,8 are rejected under 35 U.S.C. 102(e) as being anticipated by Blaeser et al. (6168617). The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131. Fig. 2 shows a stent delivery system having a catheter 18 with a balloon 22 mounted thereon. It can also be seen there is a stent 48 on the catheter. Blaeser also shows a sheath or sleeve 28 with an overlay portion that covers the stent.

The sheath also has a cone portion and waist overlay portion at its end. The sheath or sleeve also has at least one port **60**. The port is fully capable of allowing a lubricious substance to pass through it. With respect to claim 8, Blaeser discloses that a "lubricious" substance such as silicone is on the inside of the sleeve, col. 6, lines 1-3.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savin et al. (4950227) in view of Konya et al. '723. Savin et al. disclose a stent delivery system (Fig. 1) with a catheter having a balloon **14** mounted thereon and a stent **16** on a body portion of the balloon. It can also be seen the stent is held on the balloon by two sleeves (**18, 20**) with each having a stent overlay portion shown by distance **D**. Savin also discloses the sleeves are elastomeric, col. 2, lines 21-22. Savin et al. additionally disclose that a lubricating solution can be used between the balloon and sleeves, col. 4, lines 55-57. However, Savin does not disclose using ports to deliver the lubricating solution. Konya is explained supra. Konya also shows (Fig. 18) that the ports **51** are partially defined by the waist overlay portion. It would have been obvious to one of ordinary skill in the art to use the ports as taught by Konya in the sleeves of Savin et al. to provide application routes to deliver lubrication for removal of the sleeves.

***Response to Arguments***

Applicant's arguments filed 3/10/03 have been fully considered but they are not persuasive. Regarding Applicant's remarks about Konya not disclosing a "lubricious" substance, it should be noted that claims are given their broadest reasonable interpretation. In this instance, since Applicant's have not defined what a "lubricious" substance is, clearly any of the fluid materials used through the ports of Konya can be considered "lubricious". In response to applicant's argument that Konya cannot be combined with Savin, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art *cannot be the basis for patentability* when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The method of applying a lubricious substance is not at issue here, but the product. Clearly the combination of Savin and Konya result in the product as claimed. The ports are fully capable of permitting a "lubricious" substance to pass through them. The method of when a lubricious substance is applied is irrelevant to patentability of the product.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

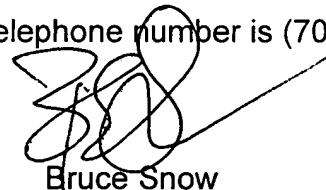
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian Pellegrino

TC 3700, AU 3738

May 14, 2003

*Brian Pellegrino*



308-0858  
Bruce Snow

Primary Examiner